

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF OHIO
WESTERN DIVISION

Ethicon Endo-Surgery, Inc.,)	
)	
Plaintiff,)	Case No. 1:05-CV-12
)	
vs.)	
)	
Tyco Healthcare Group LP,)	
)	
Defendant.)	

Memorandum and Order

In this patent infringement action, Plaintiff claims that Defendant's DST Series stapler systems infringe Claim 1 of U.S. Patent No. 4,805,823 (the "'823 Patent"). Plaintiff claims to be the sole and exclusive assignee of the entire right, title, and interest in and to the '823 Patent. This matter is now before the Court upon Defendant's motion for summary judgment on the ground that Claim 1 of the '823 Patent is invalid (Doc. 23).

Defendant bases its invalidity argument upon its assertion that Claim 1 of the '823 Patent was anticipated by prior art in the form of the ILA 52 staple cartridge originally manufactured for use in a surgical stapler known as the American V. Mueller Anastomotic Stapler. Defendant contends that the ILA 52 staple cartridge was known and used by others and in public use and on sale no later than the Summer of 1985 and was not considered by the U.S. Patent & Trademark Office during the prosecution of the '823 Patent. Because Defendant contends that the ILA 52 staple cartridge "was known or

used by others” in the United States before the alleged invention embodied in Claim 1 of the ‘823 Patent, it argues that the ILA 52 staple cartridge constitutes “prior art” with respect to Claim 1 of the ‘823 Patent in accordance with 35 U.S.C. § 102(a). Moreover, because Defendant contends that the ILA 52 staple cartridge was “in public use or on sale in this country [] more than one year prior to the date of the application for patent in the United States” for the ‘823 Patent, it argues that the ILA 52 staple cartridge constitutes “prior art” with respect to Claim 1 of the ‘823 Patent in accordance with 35 U.S.C. § 102(b). Finally, because Defendant contends that the prior art represented by the ILA 52 staple cartridge anticipates every element of Claim 1 of the ‘823 Patent, it argues that Claim 1 of the ‘823 Patent is invalid. Defendant seeks summary judgment with respect to Plaintiff’s patent infringement claim on those bases.

Plaintiff opposes Defendant’s motion. Plaintiff contends that Defendant cannot establish by clear and convincing evidence that the ILA 52 staple cartridge constitutes prior art in accordance with either § 102(a) or § 102(b) of Title 35 of the United States Code. Plaintiff further contends that the ILA 52 staple cartridge does not anticipate every element of Claim 1 of the ‘823 Patent and, thus, does not invalidate Claim 1.

A. The Summary Judgment Standard

Summary judgment is proper "if the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there

is no genuine issue as to any material fact and that the moving party is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(c). The evidence presented on a motion for summary judgment is construed in the light most favorable to the non-moving party, who is given the benefit of all favorable inferences that can be drawn therefrom. United States v. Diebold, Inc., 369 U.S. 654 (1962). "The mere existence of some alleged factual dispute between the parties will not defeat an otherwise properly supported motion for summary judgment; the requirement is that there be no genuine issue of material fact." Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 248 (1986)(emphasis in original).

The Court will not grant summary judgment unless it is clear that a trial is unnecessary. The threshold inquiry to determine whether there is a need for trial is whether "there are any genuine factual issues that properly can be resolved only by a finder of fact because they may reasonably be resolved in favor of either party." Anderson, 477 U.S. at 250. There is no issue for trial unless there is sufficient evidence favoring the non-moving party for a jury to return a verdict for that party. Id.

The fact that the weight of the evidence favors the moving party does not authorize a court to grant summary judgment. Poller v. Columbia Broadcasting System, Inc., 368 U.S. 464, 472 (1962). "[T]he issue of material fact required by Rule 56(c) . . . to entitle a party to proceed to trial is not required to be resolved conclusively in favor of the party asserting its existence; rather, all that is required is that sufficient evidence supporting the claimed factual dispute be shown to require a jury or a judge to resolve the

parties' differing versions of the truth at trial." First National Bank v. Cities Service Co., 391 U.S. 253, 288-89 (1968).

Moreover, although summary judgment must be used with extreme caution since it operates to deny a litigant his day in court, Smith v. Hudson, 600 F.2d 60, 63 (6th Cir.), cert. dismissed, 444 U.S. 986 (1979), the United States Supreme Court has stated that the "[s]ummary judgment procedure is properly regarded not as a disfavored procedural shortcut, but rather as an integral part of the Federal Rules as a whole, which are designed to 'secure the just, speedy and inexpensive determination of every action.'" Celotex Corp. v. Catrett, 477 U.S. 317, 327 (1986). According to the Supreme Court, the standard for granting summary judgment mirrors the standard for a directed verdict, and thus summary judgment is appropriate if the moving party establishes that there is insufficient evidence favoring the non-moving party for a jury to return a verdict for that party. Id. at 323; Anderson, 477 U.S. at 250.

Accordingly, summary judgment is clearly proper "against a party who fails to make a showing sufficient to establish the existence of an element essential to the party's case and on which that party will bear the burden of proof at trial." Celotex Corp., 477 U.S. at 322. Significantly, the Supreme Court also instructs that the "the plain language of Rule 56(c) mandates the entry of summary judgment, after adequate time for discovery and upon motion" against a party who fails to make that showing with significantly probative evidence. Id.; Anderson, 477 U.S. at 250. Rule 56(e) requires the

non-moving party to go beyond the pleadings and designate "specific facts showing that there is a genuine issue for trial." Id.

Further, there is no express or implied requirement in Rule 56 that the moving party support its motion with affidavits or similar materials negating the opponent's claim. Id. Rule 56(a) and (b) provide that parties may move for summary judgment "with or without supporting affidavits." Accordingly, where the non-moving party will bear the burden of proof at trial on a dispositive issue, summary judgment may be appropriate based solely on the pleadings, depositions, answers to interrogatories, and admissions on file.

B. Applicable Legal Standards

The parties agree that 35 U.S.C. § 102(a) and (b) define prior art for purposes of determining whether a patent or patent claim is invalid as having been anticipated by the prior art. Section "102 of the patent Act serves as a limiting provision, both excluding ideas that are in the public domain from patent protection and confining the duration of the monopoly to the statutory term." Pfaff v. Wells Electronic, Inc., 525 U.S. 55, 64 (1998). In accordance with § 102(a), a patent applicant is not entitled to patent protection when the invention "was known or used by others" in the United States before the asserted invention thereof by the applicant. The parties agree that the knowledge or use must be by someone other than the inventor and accessible to the public. In other words, they agree that the invention must have been known or used in a

manner that was accessible to the public before the alleged invention by the patent applicant.

A patent applicant is not entitled to patent protection, in accordance with § 102(b), if the invention was “in public use or on sale in this country [] more than one year prior to the date of the application for patent in the United States.” “Public use” is use by someone other than the inventor, or anyone under his direction, and does not include use for experimentation in order to bring the invention to perfection. See Baxter International, Inc. v. Cobe Laboratories, Inc., 88 F.3d 1054, 1059 (Fed. Cir. 1996) (citing City of Elizabeth v. American Nicholson Pavement Co., 97 U.S. 126, 134 (1877)). For the invention to have been “on sale,” it must have been “the subject of a commercial sale or offer for sale.” Abbott Laboratories v. Geneva Pharmaceuticals, Inc., 182 F.3d 1315, 1318 (Fed. Cir. 1999)(citing Pfaff, supra), cert. denied, 528 U.S. 1078 (2000).

The parties agree that “the party challenging validity must prove its case by clear and convincing evidence.” Baxter International, 88 F.3d at 1057 (citing Ryko Manufacturing Co. v. Nu-Star, Inc., 950 F.2d 714, 716 (Fed. Cir. 1991)). Clear and convincing evidence is “evidence which produces in the mind of the trier of fact an abiding conviction that the truth of a factual contention is ‘highly probable.’” Price v. Symsek, 988 F.2d 1187, 1191 (Fed. Cir. 1993) (quoting Colorado v. New Mexico, 467 U.S. 310, 316 (1983)).

As a general rule, some evidence, beyond oral testimony, must be offered by the party attempting to prove invalidity. See Finnigan Corp. v. International Trade

Commission, 180 F.3d 1354, 1366 (Fed. Cir. 1999). “Mere testimony concerning invalidating activities is received with further skepticism because such activities are normally documented by tangible evidence such as devices, schematics, or other materials that typically accompany the inventive process.” Id. (citing Woodland Trust v. Flowertree Nursery, Inc., 148 F.3d 1368, 1373 (Fed. Cir. 1998)).

C. Application

The first issue raised by Defendant’s motion for summary judgment is whether the ILA 52 staple cartridge constitutes “prior art.” Only if that device satisfies the requirements of 35 U.S.C. § 102(a) or § 102(b), does the second issue become pertinent. That second issue is whether the ILA 52 staple cartridge anticipates every element of Claim 1 of the ‘823 Patent.

Defendant identifies substantial evidence in an attempt to demonstrate that the ILA 52 staple cartridge satisfies both § 102(a) and § 102(b) vis-a-vis the ‘823 Patent. It has introduced a training video purporting to show the assembly of ILA 52 staple cartridges on August 12, 1985. That date appears on much of the video but not on a segment in which Lot Number 44516 appears. Defendant has also introduced an ILA 52 staple cartridge from that lot and argues that the configuration of the staple pocket satisfies all of the elements of Claim 1 of the ‘823 Patent. Defendant has also introduced evidence that the training video in question has been in continuous possession of ViR Engineering for twenty years.

Plaintiff does not dispute that portions of the training video may have been made on August 12, 1985, but it notes that the absence of a date on the portion of the video showing the lot number reduces the evidentiary value of the portion of the video for purposes of establishing the date upon which Lot Number 44516 was made. It also contests the similarity between the pocket configurations of the sample from Lot Number 44516 of the ILA 52 and Claim 1 of the '823 Patent. Plaintiff has not introduced evidence calling into question Defendant's evidence that the training video has been in existence and in the possession of ViR Engineering for twenty years. The Court concludes that no genuine issue of material fact exists with respect to Defendant's assertion that the ILA 52 staple cartridge from Lot Number 44516 that is in evidence was manufactured more than twenty years ago.

In February 1987, Minnesota Mining and Manufacturing Company ("3M") entered into an agreement to purchase certain assets of American Bentley, Inc. That agreement provided, among other things, that American Bentley would manufacture surgical staple cartridges for 3M. The agreement was not specific as to the models or types of such cartridges to be manufactured by American Bentley, though Defendant argues that the provision is evidence that American Bentley was continuing to manufacture ILA 52 staple cartridges as of the date of the agreement.

As further evidence that 3M continued to manufacture the ILA 52 cartridge after that agreement was entered, Defendant has submitted what purport to be manufacturing drawings of the ILA 52 from early 1988. The mere fact of the existence of

the drawings does not, of course, establish that manufacture actually occurred. Defendant has also introduced the deposition testimony of Claude Vidal and Russ Redmond, the principals of ViR Engineering, which developed the ILA 52, describing the drawings. Neither deponent testified in cited portions of his deposition, however, that the drawings correspond to a product that was manufactured at the time represented by the drawings. A former 3M employee, Sandy McMahon, testified that the staple pocket configuration, as represented in the drawings, never changed while he was employed with 3M. His employment there ended in 1989.

Considered together, then, the evidence of the drawings and the testimony relating to them stands for the proposition that the design of the staple pocket in the ILA 52 cartridge was as represented in the drawings in the period from at least early 1988 to 1989. That period encompasses the alleged invention represented in Claim 1 of the '823 Patent.¹ That evidence does not demonstrate that the cartridge was actually manufactured, sold, or publicly known during that time period.

Other evidence introduced by Defendant suggests that the design of the ILA 52 staple pocket did not change from 1983 or 1984 to the date of the agreement with 3M. Plaintiff has, however, identified evidence in the form of deposition testimony that suggests that certain revisions to the design may have occurred between 1984 and September 1987. Accordingly, a question of fact remains as to whether the configuration

¹Evidence in the form of later drawings demonstrates clearly and convincingly that the design of the ILA 52 staple pocket has not changed since that time.

of the staple pocket was the same in 1984 as in early 1988 when 3M gained possession of the rights to the ILA 52 staple cartridge. Plaintiff has not identified evidence that casts doubt upon Sandy McMahon's testimony that the pocket configuration did not change in the period beginning in early 1988 and ending with his departure from 3M in 1989.

The Court has previously discussed the videotape from 1985, which does not clearly and convincingly establish that the ILA 52 staple cartridge in its current configuration was known, sold, or used prior to the alleged invention represented by Claim 1 of the '823 Patent. Defendant has introduced other evidence, however, of knowledge, sales, or use of the ILA 52 staple cartridge prior to the alleged invention represented by Claim 1 of the '823 Patent. That evidence includes a package insert for the ILA 52 staple cartridge from March 1985. The package insert does not, without more, tend to prove that the cartridge was known, sold, or publicly used, however.

The evidence also includes a June 19, 1985, letter from then-counsel for Defendant, which did not at that time own the rights to the ILA 52 device, to counsel for American Hospital Supply Corporation, which did. In that letter, Defendant's counsel writes that Defendant "has learned that American Hospital Supply Corporation has just introduced the following new surgical stapling products: (1) V. Mueller lateral anastomosis instrument; (2) 52-staple disposable loading unit for above." While that evidence is quite suggestive, it does not amount to clear and convincing evidence because it fails to identify the ILA 52 cartridge with sufficient specificity to eliminate the possibility that the reference was to a different device. The same deficiency plagues a

series of advertisements from the Summer of 1985 in which the advertised device is identified as the American V. Mueller Anastomotic Stapler. While Defendant has introduced uncontroverted evidence that the rights to the ILA 52 device were in the possession of American V. Mueller at that time, it has failed to identify evidence establishing clearly and convincingly that the ILA 52 was the only anastomotic stapler that American V. Mueller could have been manufacturing at that time. Absent such evidence, the Court cannot conclude, on the basis of the advertisements or the letter, that the ILA 52 was publicly known in 1985.

A critical piece of evidence is a 1986 competitive reference guide produced by Defendant, which, again, was not the owner of the rights to the ILA 52 device at that time. In that document, American V. Mueller's ILA 52 staple cartridge is discussed as being offered for sale. That evidence, if authentic, demonstrates clearly and convincingly that the ILA 52 staple cartridge was known to Defendant as of sometime in 1986 at the latest. As the Court has noted, the issue of whether the staple pocket configuration of the ILA 52 staple cartridge was the same then as in 1988 and 1989 is not subject to resolution by clear and convincing evidence at this stage of this litigation. If Defendant is able to prove at trial that the device that is the subject of the 1986 competitive reference guide did not change between that time and the period between 1988 and 1989 when Sandy McMahon was employed by 3M, it will quite likely be able to prove that the ILA 52 staple cartridge was "known . . . by others" in the United States before the asserted

invention represented by Claim 1 of the '823 Patent for purposes of establishing its invalidity defense under § 102(a).²

A letter from Sandy McMahon of 3M to Claude Vidal of ViR Engineering in May 29, 1987, stands equally for the proposition that the ILA 52 staple cartridge was in use in the period of six months preceding the date of that letter. Mr. McMahon writes that Metro Medical Center in Minneapolis had stopped using the ILA 52 staple cartridge due to a problem with homeostasis. To the extent that the letter constitutes admissible evidence, it is clear and convincing evidence that the ILA 52 staple cartridge was “in public use” in the late 1986/early 1987 period. That fact does not establish the invalidity defense under § 102(b), however, in the absence of clear and convincing evidence that the pocket configuration of the ILA 52 staple cartridge was the same then as in 1988 and 1989 when 3M possessed the rights to the device and Sandy McMahon was employed by 3M.³

Because Defendant has not established the first element of the invalidity defense under either § 102(a) or § 102(b), the Court need not consider whether the second element is established. For present purposes, the Court notes only that the staple pocket of the sample of the ILA 52 staple cartridge introduced as evidence in this matter is

²Defendant has not introduced evidence of use, knowledge, or sales during the period beginning when 3M acquired the rights to the ILA 52 staple cartridge and ending with the filing of the application for the '823 Patent.

³Defendant has argued that the sample from Lot Number 44516 is evidence that the pocket configuration was the same in August 1985 as at present. It has not identified clear and convincing evidence, however, that every unit from Lot Number 44516 was produced at one time or, indeed, that Lot Number 44516 included more than one unit. The evidence presently identified by Defendant, while quite suggestive, does not satisfy the clear and convincing standard.

indistinguishable from that in Claim 1 of the '823 Patent. The Court recognizes, however, that some of the deposition testimony of the inventors of the ILA 52 device is contradictory with respect to the shape of the staple pocket.

D. Conclusion

For those reasons, Defendant's motion for summary judgment of invalidity (Doc. 23) is hereby **DENIED**.

IT IS SO ORDERED.

/s/
Sandra S. Beckwith, Chief Judge
United States District Court